Summary Minutes of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel Public Meeting
November 12, 2003, 8:30 AM – 5:30 PM & November 13, 2003 8:30 AM – 12:30 PM
Clarion Hotel, Research Triangle Park, North Carolina

Panel Members: See Panel Roster – Attachment A.
Date and Time: Tuesday, November 12, 2003, 8:30 AM – 5:30 PM;
Wednesday, November 13, 2003, 8:30 AM – 12:30 PM
Location: Clarion Hotel, 4912 South Miami Boulevard,
Research Triangle Park, North Carolina

Purpose: The purpose of this meeting was for the CASAC PM Review Panel to: (1) discuss follow-on matters related to its ongoing peer review of the EPA Air Quality Criteria Document for Particulate Matter (Fourth External Review Draft); and (2) conduct a peer review of the Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific Technical Information (OAQPS Staff Paper – First Draft) and a related draft technical report, Particulate Matter Health Risk Assessment for Selected Urban Areas (Draft Report).

Attendees:

Chair:	Dr. Philip Hopke
CASAC Members:	Dr. Frederick Miller
	Mr. Richard Poirot
	Dr. Frank Speizer
	Dr. George Taylor
	Dr. Sverre Vedal
	Dr. Barbara Zielinska
Consultants:	Dr. Petros Koutrakis
	Dr. Allan Legge
	Dr. Morton Lippmann
	Dr. Roger McClellan
	Dr. Gunter Oberdorster
	Dr. Robert Rowe
	Dr. Jonathan Samet
	Mr. Ronald White
	Dr. Warren White
	Dr. George Wolff
EPA SAB Staff:	Mr. Fred Butterfield, DFO
	Dr. Vanessa Vu, SAB Staff Office Director

Others attending:

Linnea Avallone, University of Colorado / Environmental Defense
John Bachman, U.S. EPA, OAQPS
Brian Baldwin, Southern Co.
Barbara Bauer, E.H. Pechan
Tim Benner, U.S. EPA, ORD
Charlotte Bertrand, U.S. EPA
Kurt Blase, O'Connor and Hannan
Wayne Cascio, University of North Carolina, Chapel Hill
Bob Connery, Holland and Hart LLP
Dan Costa, U.S. EPA, ORD, NHEERL
Rich Damberg, U.S. EPA, OAQPS
Alison Davis, U.S. EPA, OAQPS
Leland Deck, Abt Associates
Robert Fegley, U.S. EPA, ORD
Steve Gavett, U.S. EPA, ORD, NHEERL
Les Grant, U.S. EPA, ORD, NCEA
Laura Green, Cambridge Environmental, Inc.
Tim Hanley, U.S. EPA, OAQPS
Mary Harmon, U.S. EPA, OAQPS
Stan Hayes, ENVIRON International Corporation
Jon Heuss, Air Improvement Resource (AIR), Inc.
Marion Hoyer, U.S. EPA, OTAQ
Phil Johnson, Northeast States for Coordinated Air Use Management (NESCAUM)
Martha Keating, Clean Air Task Force
Rebecca Klemm, Klemm Analysis Group, Inc.
Dennis Kotchmar, U.S. EPA, ORD, NCEA
Cindy Langworthy, Hunton and Williams
Allen Lefohn, A.S.L. & Associates
Fred Lipfert, private citizen
Neil MacIntyre, American Thoracic Society
Karen Martin, U.S. EPA, OAQPS
Scott Mathias, U.S. EPA, OAQPS
Tom McCurdy, U.S. EPA, ORD, NERL
David McKee, U.S. EPA, OAQPS
Douglas McKinny, U.S. EPA, ORD, NRML
David Menotti, Shaw Pittman
David Mickey, Blue Ridge Environmental Defense League
Andy Miller, U.S. EPA, ORD, NRML
Jiri Novak, CHMI
Will Ollison, American Petroleum Institute
Joseph Pinto, U.S. EPA, ORD, NCEA
Ellen Post, Abt Associates
Michael Reale, Daimler Chrysler
John Richards, Air Control Techniques

Harvey Richmond, U.S.EPA, OAQPS
Mary Ross, U.S. EPA, OAQPS
Bill Russo, U.S. EPA, ORD, NHEERL
Baiyina Salahuddin, Labcorp
Vicki Sandiford, U.S. EPA, OAQPS
Greg Schaefer, Arch Coal, Inc.
Deborah Shprentz, American Lung Association
Steve Silverman, U.S. EPA, OGC
Anne Smith, Charles River Associates, Inc.
Joe Suchecki, EMA
Geoffrey Sunshine, Health Effects Institute
David Svendsgaard, U.S. EPA
Jay Turim, Sciences International, Inc.
Peter Valberg, Gradient Corporation
John Vandenberg, U.S. EPA, ORD, NCEA
Amy Vasu, U.S. EPA, OAQPS
Pamela White, JHBSPH
William Wilson, U.S. EPA, ORD, NCEA
Ron Wyzga, Electric Power Research Institute
Louis Zeller, Blue Ridge Environmental Defense League

Meeting Summary

The discussion generally followed the issues and general timing as presented in the meeting agenda (Attachment B), except for minor changes in the scheduling of public speakers as noted in the minutes.

WEDNESDAY, NOVEMBER 12, 2003

Convene Meeting, Attendance, Introduction and Administration

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the CASAC, opened the meeting and welcomed those present on behalf of the Agency. He noted that the CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA) to provide advice and recommendations to the EPA Administrator. Consistent with FACA requirements, its deliberations are held as public meetings for which advance notice is given in the *Federal Register*. The DFO is present at all such meetings to assure compliance with FACA requirements. Minutes and a transcript were recorded for this meeting. The minutes will be certified by the Panel Chair and made available on the SAB website. However, the Agency cannot certify the accuracy of transcripts. All Panel members have submitted financial conflict of interest information, which was reviewed for any appearance of lack of impartiality.

Dr. Vanessa Vu, SAB Staff Office Director, thanked the Chair and members of the CASAC PM Review Panel for their efforts and advice to the Agency on these documents, and Agency

representatives who would be presenting information during the meeting. She also thanked the SAB and EPA staff who organized the meeting.

Mr. Butterfield informed attendees that twenty-three public speakers would be providing their comments later in the day, and noted that comments should be limited to five minutes per speaker. He reviewed meeting logistics and introduced the CASAC Chair, Dr. Phil Hopke.

Purpose of Meeting

Dr. Phil Hopke, CASAC Chair, noted that the Panel would be receiving an update on the status of the PM criteria document, as well as reviewing the first draft of the staff paper. The latter would take up the majority of the Panel's time during the meeting.

Update on PM National Ambient Air Quality Standards (NAAQS) Review Schedule

Dr. Karen Martin (EPA/OAQPS) distributed the updated schedule for review of the PM NAAQS (see Attachment E), highlighting the key milestones. She noted in particular the three commitment dates for the Agency. The final criteria document is currently due on December 19, 2003. The Agency understands that it is neither appropriate nor feasible to complete peer review and produce a final document by that date. The Agency is engaged in discussion with the plaintiffs (who filed a complaint in the U.S. District Court for the District of Columbia on March 31, 2003) and has received the following initial positive response to the Agency's request to extend the completion of the criteria document to April 30, 2004: "With the understanding that the multi-year Criteria Document development process will finally be brought to conclusion by April 2004, plaintiffs are inclined — although reluctantly — to agree with EPA's extension request." Discussions also recognized the interim milestones for completing the staff paper would change. Dr. Martin noted that a 2nd draft staff paper would not be prepared until such time as it can be based on the final criteria document. The other two commitment dates listed are the deadlines for the notice of proposed rulemaking (March 31, 2005) and notice of final rulemaking (December 20, 2005). These dates are not being changed, as it is too early to predict any impact on the proposal and rule making at this time.

Update on Revisions to EPA's 4th Revised Draft Air Quality Criteria Document for PM

Dr. Les Grant (EPA/ORD/NCEA) presented an update on revisions being made to the 4th Draft Air Quality Criteria Document (AQCD) (see Attachment F). He noted that the outcome of the Panel's August 2003 meeting was a decision that review was completed on Chapters 1 through 5. Chapters 6, 7 and 8 required more substantive revisions; once revised, these chapters will be sent to members of the Panel for a limited review. Chapter 9 required major re-writing, and will undergo public comment and full CASAC review upon its completion.

The writing team anticipates having editorial changes in the first five chapters completed over the next several weeks. Additional materials for Chapter 6 (Dosimetry) have been provided to

the Panel's designated reviewer, Dr. Fred Miller. The entire chapter, however, will not undergo further comment or review. Chapters 7 and 8 have involved more extensive efforts than initially expected, and will be discussed in more detail. Both chapters will be revised and submitted to the CASAC for further comment. Chapter 9 and the Executive Summary would draw upon revisions made to all other chapters. Dr. Grant then presented additional information on the revisions being made to Chapters 6, 7, and 8.

In Chapter 6, revisions are being made to the section entitled "Dosimetric consideration in Comparing Dosages for Inhalation, Instillation, and Exposure of Cultured Cells." The section now provides a qualitative perspective on important factors for evaluating levels of experimental exposures and relating them to inhalation deposition at ambient levels of PM. Quantitative dose calculation information and extrapolation comparisons will be added to Chapter 7. The section (in Chapter 6) on the results of dosimetry calculations using publicly available models is also being revised to reflect new results, and a comparison added of regional deposition fractions as a function of particle size for two dosimetry models.

Chapter 7 discusses the toxicology of particulate matter. In the discussion of doses, both the tabular presentation and text discussion of doses used in laboratory animals and humans is being revised. Explicit information will be given, whenever possible, on the doses at which effects were observed. Extensive efforts are being devoted to extrapolation modeling, which is being used to compare estimates of doses delivered to (and also doses retained in) regions of the respiratory tract tissues under various experimental exposure regimens. Illustrative examples will be given from research conducted by EPA scientists (Drs. William Wilson, Dan Costa, and Steve Gavett).

The discussion on the mechanisms and pathways of PM's relationship to cardiovascular disease (CVD) is being expanded to add a schematic representation, noting in particular the two different pathways by which cardiovascular effects occur. One such pathway is mediated through PM's impacts on the autonomic nervous system, while another involves the activation of a clotting cascade, and can potentially lead to thrombosis events. The CASAC had recommended that the Agency seek outside medical expertise on this topic.

EPA staff drew upon expert consultation from cardiac medicine expert Dr. Wayne Cascio, whose comments were similar to those submitted by one of the public commenters, Dr. Venditti. Most studies indicate heart rate variability (HRV) changes are not directly causative of serious cardiac outcomes, but can be considered an index of underlying cardiac pathology, which could contribute to an increased risk of such outcomes. They are more clearly established as likely predictors of long-term risk of serious outcomes, rather than near-term cardiac events. The overall opinion is that comparing across studies on HRV and PM is not a simple matter, but rather requires careful examination of all the studies considered.

In Chapter 7, the relationship between HRV changes and potential cardiac outcomes will be better explained, and the human and animal PM exposure studies using HRV measures will be evaluated. Links will be included to the discussions in Chapters 8 and 9 of panel studies and other epidemiological analyses of the possible effects of ambient PM on HRV and other cardiac

endpoints. However, more research is necessary in order to better characterize these cardiac effects.

Dr. Speizer asked whether the document would indicate which aspects of HRV are most predictive, or focus on studies examining this question. Dr. Grant explained that he would examine studies that look at the pattern of HRV results, as well as make distinctions between the implications of near-term versus long-term risk.

Dr. Koutrakis commented on the different treatment of cardiac effects, compared to what has been traditionally measured for pulmonary/respiratory illness. Dr. Miller explained that the CASAC had asked the Agency to seek assistance from a cardiologist, as the information related to changes in HRV is difficult to understand.

Dr. Cascio added that heart rate variability is an effective way to non-invasively evaluate the neurological input to the heart. Although heart rate variation is normal, a sustained decrease in HRV is linked with a higher risk of death. There is also accumulating information that modulating HRV in the short term is associated with non-life-threatening rhythm disturbances. It is not known, however, what implication a transient increase in HRV may have with respect to life-threatening risk.

Dr. Samet noted that Dr. Koutrakis' comment was related to the inconsistency in handling the two biomarkers of response: cardiac and pulmonary effects, at the population level.

Dr. Grant explained that varying information and levels of confidence exist in using biomarkers and indicators. The difficulty in using these lies in part in capturing important distinctions and nuances. In the case of HRV, the Agency has made some further progress in addressing these issues, and that is one of the messages conveyed in the document.

Dr. Grant continued his presentation, moving to the summary of revisions planned for Chapter 8. One key change would be editing the textbook-type discussion of confounding concepts and the interpretation of analytic approaches to a more comprehensible and concise format. The discussion of GAM reanalyses will be expanded to include more information on single-city reanalyses results. The section on intervention studies will also be revised to add new studies and more clearly portray the results of all the assessed studies.

Dr. Grant concluded by noting that discussion of Chapter 9 (Integrative Synthesis) would not be relevant at this time, as its content will depend on the finalized Chapters 1-8.

In response to Dr. Wolff, Dr. Grant confirmed the authors of Chapter 8 would also further examine the long-term studies.

Dr. William Wilson (EPA) then presented slides showing results from extrapolation modeling studies (see Attachment G). He presented a comparison of regional deposition results and PM deposition in respiratory tissues.

Dr. Lippmann commended the effort to further interpret existing data, but noted that deposition in respiratory tissues will not be uniform, as these particles rarely deposit on most of the alveolar surfaces. Dr. Miller agreed that there is more complexity in these relationships than the graphs can represent, but noted it is important to put animal studies in perspective with humans, even if some general assumptions need to be made.

Dr. McClellan cautioned that the curves presented, though useful, could be misinterpreted, as they are hypothetically related to a distribution of particle sizes. Dr. Wilson agreed, and noted there is some discussion of this issue in Chapter 7. He also agreed with Dr. Koutrakis' remark that models do not take into account increases in deposition rates arising from the hygroscopic nature of particles. In response to Dr. McClellan's requests, Dr. Wilson agreed to provide information comparing regional deposition fractions for both monodisperse and typical polydisperse size distributions. A discussion of the significance of relative humidity would also be added.

Dr. Wilson noted that lung surface area was normalized by adjusting to the lung functional residual capacity, so that a comparable surface area could be used in comparisons.

He then noted that the CASAC had recommended adding rat-to-human extrapolation modeling information to Chapter 7, in an effort to determine what human exposure is comparable to doses administered to rats in animal studies. Dose metrics can be normalized in many different ways: in terms of mass, particle surface area, or particle size; or in terms of total dose, average dose, deposited dose or retained dose. Several different ways of normalizing will need to be considered.

Dr. Wilson presented plots comparing the human and rat ratios of total deposited dose, accumulated in 6-hour exposure intervals over three days. A higher dose is retained in the tracheobronchial region of the human than the rat and clearance is slower in the human. Chronic exposure was also examined using modeling. Rats will reach a plateau after a few months of exposure; humans only approach a similar plateau after ten years – the maximum run time permitted by the model. Other such discrepancies must be accounted for when comparing rat to human exposure. Laboratory rats are exposed while at rest, while humans could be engaged in a variety of activities. There are also differences in the size distribution of particles: whereas rats are exposed in the lab to re-suspended dust, humans breathe in particles of different sizes from the atmosphere.

Graphs depicting surface area distribution show somewhat higher surface area accumulation of coarse particles in rats than in humans. Even with this higher accumulation, rats must be exposed to very high ambient concentrations if they are to receive doses comparable to humans. Other considerations in comparing the two are more general. Most laboratory rats used in studies are mature, healthy individuals; in humans, there exists a variety of pre-existing heart, lung, or other diseases. Nutritional status may also play a role, as can the fact that animals kept in relatively clean laboratory environments carry a smaller baseline burden of PM than humans.

Dr. Wilson reviewed the approach chosen for extrapolation from rats to humans, including the breathing pattern to be used, exposure scenarios, and the factors proposed to normalize rat and

human tidal volume and respiratory tissue deposition/accumulation. He noted that other scenarios and approaches would also be considered in continuing this research.

Dr. McClellan remarked that rats have a diurnal pattern of activity, much like humans, and noted that assumptions such as resting state during lab studies should be carefully examined. Dr. Wilson agreed, but explained that a specific setting had to be selected.

Dr. Miller commented that the information presented was useful, but there may be some merit in including selected examples in the document as an illustrative, rather than exhaustive discussion.

Dr. Lippmann commended the inclusion of these comparisons, noting that this is the type of work that should have been conducted years ago. He cautioned that the re-suspended material used in rat studies is very different, and likely less active, than material still in the atmosphere. The implications of this may need to be discussed.

Dr. Oberdorster noted that the Multiple Path Particle Dosimetry (MPPD) model is the best one available for comparison. He recommended that differences in the treatment of rats versus humans in other models should be pointed out.

Dr. Grant added that there is no available model that can make scale calculations to take into account compromised human populations. In the absence of such a model, the best possible approach is to describe qualitatively the evidence that implies compromised humans show higher deposition than healthy rats. He reiterated that dose metrics have identified that the very high concentrations used in rat studies may still not be equivalent to human exposure.

Dr. Lippmann suggested using concentrated ambient particles (CAPs), as there is a growing body of literature on CAPs inhalation studies in rats. Dr. Wilson agreed, but noted one of the problems may be finding an appropriate size distribution for CAPs.

Dr. McClellan praised the Agency's efforts on further researching this topic, and recommended including a few examples in the criteria document. He added that he would encourage continuing this research outside of the CD efforts. Dr. McClellan expressed the view that, although this is an important topic, it is not critical in terms of setting the national air quality standard.

Dr. Miller disagreed, expressing the view that this topic is important in terms of reviewing the standards. Dr. Hopke noted that it is appropriate and necessary for the CD to adequately summarize relevant scientific knowledge. He added that the question for the Panel is whether the information is sufficient to finalize this chapter.

Dr. Dan Costa (EPA) then continued the update on the CD revisions by discussing how high concentration inhalation and intra-tracheal (IT) instillation studies are related to the health assessment of PM (see Attachment H). Inhalation studies often use high concentrations, relative to ambient PM. IT instillation studies generally use high doses, administered using a "bolus" delivery. Such studies are conducted for hazard identification, model development, or to define

reproducible effects and establish potential models of action. The studies were in general not designed for risk estimation.

Studies used included the Pope, 1989 study on the Utah Valley experience, which compared exposures before, during, and after the closing of a nearby steel plant. The Utah Valley toxicology studies using particles collected during the same time period as the epidemiology studies were crucial in providing biological support for epidemiology studies. Information was also gathered from research on CAPs and PM, including studies by Ghio *et al.* (2000) and Kodavanti *et al.* (2001 and 2003). These used the instillation approach, and humans were shown to achieve doses equivalent to those used in rats when exposed to 67% of the estimated rat inhalation exposure.

An inhalation head-to-head comparison was then conducted using 10 mg of residual oil fly ash (ROFA), based on summed dose from the two lung lobes (treated independently). Data were presented illustrating ROFA concentration in bronchoalveolar lavage fluid (BALF) for a range of doses. ROFA distribution was similar for inhalation and IT instillation, and proportionate to lung lobe size. Graphs were also presented illustrating 24-hour pathology of the airway and alveoli (inhalation vs. instillation), and airway hyper-reactivity at different time points.

Dr. McClellan cautioned that using the term "EPM" could be confusing, adding that he prefers the use of "ROFA." Dr. Costa noted that all ROFA particles are not the same.

CASAC PM Review Panel Discussion and Deliberations re: PM AQCD

Chapters 6 and 7

Dr. Hopke commented that the Panel should decide whether the revisions proposed adequately address the Panel's previous comments. He added that, in his opinion, some limited examples would be sufficient; these have been included, and it is now a question of presenting them adequately. He solicited the opinions of other Panel members on this matter.

Dr. Lippmann asked the opinion of Dr. Grant and Dr. Wilson, with respect to how useful they have found the Panel's input. He asked for the Agency's comments on whether they could continue the work of making better use of the science on deposition and toxicology.

Dr. Grant replied that the most recent discussion demonstrates that there is not one correct way of approaching this topic. The recommendations of the Panel were followed, such as using the MPPD model, but the Agency does not have the resources to undertake a multiple-year study. The examples and results presented today will be incorporated into the document, and a revised chapter 7 will be made available for public comment and CASAC review. He added that he hoped the Panel would agree that the revisions outlined today are adequate. If they are not, the Agency would need very specific recommendations on any additional work.

Dr. McClellan commented that he was impressed with the work presented, though the chapters can be strengthened, specifically by validating some of the models used. He noted that there

may be a dataset available to use for that purpose, and suggested also a direct comparison between the MPPD, ICRP, and NCRP models. The issue of relating model dispersed particles to real world scenarios could also be clarified.

Dr. Grant noted that the CASAC has provided suggestions on how quality should be described, and these are taken into account in the revisions.

Dr. Miller disagreed with adding the NCRP model in the comparison suggested by Dr. McClellan, as it is very similar to the ICRP model. Dr. Hopke agreed with Dr. Miller, but noted that the comparison of MPPD and ICRP should be conducted, and should utilize poly-dispersed particles.

The Panel agreed, and proceeded to the review of Chapter 8.

Chapter 8

Dr. Vedal noted that the Panel had provided a detailed response to Chapter 8 the last time it was reviewed, and would assume that at least the errors identified would be corrected. Another important topic is the interpretation of the multi-pollutant results, which requires the use of judgment by the chapter authors and may be a variation of a sensitivity analysis. Finally, the selection of the single-city models is critical; as it is not practical to include all such studies, some criteria are needed to outline why the studies included were chosen.

Dr. Grant replied that the list of studies used included those in the U.S. and Canada; from this list, those most directly relevant to decision making for the U.S. would be selected. He agreed with Dr. Vedal's comment on sensitivity analysis for the multi-pollutant model results.

Dr. Miller thought that the staff paper may be a more appropriate document for including sensitivity analysis discussion. Dr. Hopke commented that the Agency may not have the time to conduct a full sensitivity analysis.

Dr. Vedal explained that he was not suggesting a full sensitivity analysis, but rather a discussion of how consistent and robust the results of the multi-pollutant model studies are. He added that including this in the CD would enhance the value of the epidemiology information.

Dr. McClellan suggested also using one of the studies which have robust analysis as an example, so that non-experts can understand how the multi-pollutant studies were used. He agreed that balanced coverage of all relevant studies in the CD would be appropriate, because of its linkage to the staff paper. On a separate topic, he noted that the nature of the concentration-response function should be discussed more thoroughly, and possibly come under a chapter heading.

Mr. R. White commented that the criteria used for the selection of studies should be clearly stated, and the selection process explained in a transparent fashion.

Mr. Poirot suggested emphasizing the complexity of the multi-pollutant models, and the fact that they can be influenced by seasonal differences in pollutant concentrations and other confounding factors. Dr. Lippmann agreed, but noted that some studies could also over-compensate for seasonal effects. He added that there were other caveats that need to be stated, such as the fact that pollutants penetrate indoors – where people spend the majority of their time – at different rates and concentrations.

Dr. Hopke stated that the Panel's report from the August 2003 meeting was in its final stages, and that he expected to send the final version to all Panel members by Friday, November 14th. He asked members to return their comments to him by the following weekend, November 15-16 [these dates were later modified – see Action Items]. The official report will then be sent to the Agency early in the week of November 17th.

Dr. Grant then presented the Agency's expected schedule for completing the CD. Final revisions to Chapter 6 are nearly complete, and should be finalized by next week (November 17-21). Revisions to Chapters 7 and 8 are expected to be finished around the end of November, and likely to be available for CASAC review and public comment in early December. A teleconference with the Panel may be needed to discuss these two chapters in mid-January 2004. The Agency will also continue to work on Chapter 9. A revised draft of Chapter 9 will not be completed until after the teleconference with the Panel, and should be available in mid to late January 2004. It will then be sent out for CASAC review and for public comment simultaneously, and is projected to be reviewed by CASAC at a public meeting around the beginning of March 2004.

Dr. Hopke commented that this was an ambitious schedule, but January 15th (mid-January) is an appropriate target date for completing Chapter 9 and sending it out for public comment. He confirmed that February 15, 2004 would be the earliest date the Panel could meet again, in order to allow thirty days for the receipt of public comments. He noted that this would be a one-day face-to-face Panel meeting. Dr. McClellan added that this meeting should take place no later than March 1 2004, so that the Agency can meet the April 2004 deadline.

Dr. Miller asked that this meeting be scheduled to not conflict with the meeting of the Society of Toxicology, and agreed to send the exact dates of this meeting to the DFO.

Dr. Hopke added that, assuming the CD is finished in April, he expected that the second draft staff paper would be available for review during the July to August 2004 time period.

Public Comment Period re: PM AQCD and PM Staff Paper & Risk Assessment

Mr. Butterfield began the public comment period and reminded speakers to keep their statements brief, particularly those who had already submitted written comments (see Attachment I for a list of all public speakers).

Dr. Neil MacIntyre, American Thoracic Society (ATS)

Dr. MacIntyre stated that the ATS believes the science behind the proposed standard is sound and compelling, and provides sufficient confidence to move forward with decision making to protect public health. Though the ATS endorses EPA's overall findings, it believes a statement on page 101 of the staff paper should be reviewed. It states that the mechanisms between particle exposures and health outcomes have not been demonstrated. Although this was true at the time of the last document, more research has since been published (e.g., by Peters *et al.*). The ATS recommended the creation of two distinct pollution standards, for fine as well as coarse particles; lowering of both the upper and lower threshold for the annual average PM standard; re-evaluation of spatial averaging, which fails to provide adequate protection for populations near high concentration areas (hot spots); and consideration of an alternative to the 98th percentile rule, which allows too many exceedance days prior to reaching the 24-hour standard. Dr. MacIntyre concluded by thanking the Panel and commending EPA on its work on the staff paper.

Dr. Jay Turim (Sciences International) for the Coalition for Coarse Particle Regulation

Dr. Turim commented on the staff paper on behalf of the Coalition for Coarse Particle Regulation (see Attachment J). The staff paper's recommendations for a coarse particle standard are based on a sparse data set; few supporting studies are cited, some of which are not robust or do not address important issues. In addition, the interpretation of some of the cited research is dubious (e.g., Gauderman *et al*., Burnett *et al.*). Though a wide range of studies are listed in the document's Appendix A, the staff paper is selective in the studies chosen to support the $PM_{10-2.5}$ standard. In addition, many of the cited studies do not take into account important confounding variables, such as weather, co-pollutants, or PM composition. There is poor agreement between the staff paper, criteria document, and the risk assessment (RA), with various documents citing different studies for different purposes, and the role of the RA is dubious, having not been used in setting the recommended standard. The staff paper is also deficient in its discussion of uncertainties, a basic component of any risk assessment and one that would allow decision makers a fair view of the various data shortcomings. The data presented simply do not support a coarse particle standard.

Dr. John Richards (Air Control Techniques) for O'Connor and Hannan, LLP

Dr. Richards presented comments on behalf of the National Stone, Sand and Gravel Association (NSSGA) (see Attachment K). The NSSGA does not believe the ambient $PM_{10-2.5}$ data compiled and evaluated by EPA provide an adequate basis for policy decisions. Data quality issues include the lack of a Federal Reference Method (FRM) for $PM_{10-2.5}$ ambient monitoring, data uncertainties, and inadequate geographical coverage of ambient concentration data. The NSSGA has been collecting $PM_{10-2.5}$ monitoring data since 1995 which are representative of NSSGA's more than 10,000 facilities across the U.S. These data have revealed $PM_{10-2.5}$ to PM_{10} ratios to be 70%-85%, considerably higher than the 60% values indicated in the staff paper. Geographic variations could result in large portions of the rural and agricultural Midwest, Southwest, and West being found in non-attainment with a $PM_{10-2.5}$ based on erroneous and incomplete data. The NSSGA recommended the development of an accurate and reliable FRM for $PM_{10-2.5}$; deployment of $PM_{10-2.5}$ monitors in a wide range of geographical locations; and a delay in setting

the $PM_{10-2.5}$ standard until such time as accurate and representative data are available from all regions of the country.

Mr. Greg Shaefer (Arch Coal) for O'Connor and Hannan, LLP

Mr. Shaefer noted that Arch Coal operates coal mines in the United States and has been conducting monitoring for coarse PM (see Attachment L). Monitoring data from the Southern Powder River basin in Wyoming, using the PM_{10} FRM showed coarse particles to comprise 70% of those collected in TEOM monitors – consistent with the 70%-85% value just presented by the NSSGA. The supporting research cited in the criteria document and staff paper does not justify a need for a reduction in the coarse PM standard. Rural areas will likely be unable to meet a more stringent standard, as the $PM_{2.5}$ to PM_{10} ratio in those regions often exceeds 100%. In addition, there is no FRM for coarse PM, and subtracting $PM_{2.5}$ from PM_{10} is not a regulatory option.

Mr. Robert Connery (Holland & Hart LLP) for the National Cattlemen's Beef Association

Mr. Connery presented comments regarding the coarse PM standard (see Attachment M). He noted that a coarse PM standard cannot be supported due to confounding factors and measurement errors, arising from the fact that coarse PM particles can be included in the fine PM measured by monitors. Key studies of coarse PM have other measurement limitations that render them insufficient to support a coarse PM standard. Other studies have shown no association between coarse PM and increased mortality or morbidity. In addition, coarse PM exposure cannot be inferred from stationary central monitoring stations on which the draft CD's conclusions on mortality and morbidity rely. These flaws critically undermine any adequate basis for a coarse PM standard

Dr. Allen Lefohn, A.S.L. & Associates

Dr. Lefohn stated that he had submitted a report to EPA on the staff paper in addition to his oral comments (see Attachment N). He stated that, in order to derive scientifically defensible standards for $PM_{2.5}$, the Agency should have first established dose response relationships between reported ambient PM and actual PM exposures. Although the standard is based on mean annual concentration, there is no evident relationship between mean concentration and human health endpoint data. Data were presented showing no such relationship for a variety of health endpoints, for both the annual and 98^{th} percentile standards.

Mr. Stanley Hayes (ENVIRON International Corporation) for the Alliance of Automobile Manufacturers (AAM)

Mr. Hayes reviewed the staff paper for the AAM and presented four main points (see Attachment O). The confounding effects of seasonality/time and weather contribute to unresolved uncertainty in the effects of PM. The effect of PM is also heterogeneous among cities, thus findings from one locale cannot be generalized to other cities or regions; these differences among cities have implications on both standard setting and control strategy design. Refinements need to be made to the PM risk assessment: caution should be exercised in using Bayesian adjusted risk, and the lower bounds of the confidence intervals should not be truncated. Finally, the RA

results should be linked into the choice of ranges and standard selection to provide better rationale for the NAAQS concentration range.

Ms. Deborah Shprentz, American Lung Association (ALA)

Ms. Shprentz thanked the Agency for providing the opportunity for public review and comments and stated that EPA and the CASAC should preserve and strengthen the policies that have been proposed on the draft criteria document and staff paper. The scientific evidence presented clearly supports more stringent standards. From a public health perspective, the ALA believes that the highest priority must be paid to strengthening the annual average fine particle standard. Each microgram that EPA lowers the annual average fine particle standard will save literally thousands of lives each year. Clear evidence supports EPA lowering the bottom end of the range for this standard, to accommodate margin of safety considerations. The ALA also believes that high priority should be placed on the 24-hr $PM_{2.5}$ standard. The lower end of this standard's range must extend to at least 25 $\mu g/m^3$. Furthermore, EPA should consider alternative forms, as the current 98^{th} percentile standard, which permits twenty-one days of unlimited pollution, fails to protect the public. The ALA also agrees with the need for a separate coarse PM standard, but would like to see additional analysis to inform the decision-making process, particularly at concentration levels below those proposed by EPA. Additional analysis is also needed to examine whether spatial averaging is an appropriate form for setting standards.

Dr. Ron Wyzga, Electric Power Research Institute (EPRI)

Dr. Wyzga focused his comments on the uncertainty tied to the modeling used in the staff paper, criteria document, and risk assessment (see Attachment P). In the time-series studies, results can depend on temporal adjustment and the level of effects can vary; it is unclear which model is the preferred one to use, and there is no easy way to predict variability. In the ARIES studies, data for mortality and hospital admissions predicted by the model differed significantly from the observed data. This modeling uncertainty, and the potential differences arising from using one model over another, should be recognized and incorporated into the RA

Dr. Rebecca Klemm, Klemm Analysis Group, Inc.

Dr. Klemm discussed the sensitivity and variability of modeling results (see Attachment Q). The estimated effects of $PM_{2.5}$ are sensitive to model formulation, a fact that should be explained in the staff paper. The relative magnitude of these estimated effects also varied by study area and the number of knots used to smooth time. It is important to point out these study area variations when discussing combined estimates: these estimates should only be quoted if the details of the individual estimates are provided as well. Frequently, positive estimated effects calculated using different methods do not confirm each other, nor do they demonstrate equivalence. Negative effects, on the other hand, tend to be more difficult to publish. Finally, the magnitude of the estimated effect is important.

Dr. Laura Green (Cambridge Environmental, Inc.) for ExxonMobil

Dr. Green provided comments on the chemistry and toxicology of airborne PM (see Attachment R). She noted that, although epidemiology studies provide some support for the premise that reducing ambient PM will decrease mortality, no such evidence exists from acute or chronic toxicology studies, or from the chemistry of PM. Essentially all the PM forms of regulatory interest are the primary or secondary products of combustion; yet the lethal substances produced during combustion are all gases or vapors – PM does not play a role in combustion toxicology. No lethality has been reported for many forms of ambient PM, including elemental carbon, sulfates, nitrates, and concentrated ambient particles (CAPs). Chronic studies in various animal models have also shown no basis for assuming that ambient concentrations of diesel PM cause premature death in any species. Airborne PM components have also been evaluated and regulated by Agencies including the National Institute for Occupational Safety and Health (NIOSH), whose recommended exposure limits for different forms of PM can vary by as much as five orders of magnitude (e.g., beryllium vs. ammonium sulfate?). Finally, known confounding factors were not adequately considered in estimating risk to humans from ambient particulate matter.

Mr. Phillip Johnson, Northeast States for Coordinated Air Use Management (NESCAUM)

Mr. Johnson provided comments on the staff paper, and particularly on the nature of the standards proposed (see Attachment S). NESCAUM agrees with the need for a protective primary annual $PM_{2.5}$ standard, as well as a protective daily $PM_{2.5}$ standard. The latter should be consistent with the annual and provide both an adequate safety margin for populations, and uniform Air Quality Index health messaging. EPA should pursue further research on sub-daily health impacts of airborne particles, toward the possibility of addressing this exposure timeframe in future regulations. Finally, a secondary standard is needed to address the considerable environmental deterioration caused by $PM_{2.5}$; this secondary standard should take visibility impairment into consideration.

Mr. Louis Zeller, Blue Ridge Environmental Defense League (BREDL)

Mr. Zeller presented comments on the staff paper (see Attachment T), and noted that BREDL believes the PM standards adopted by EPA in 1997 are inadequate, as they are based on three years of data and spatial averaging. Further, many counties are likely not meeting these standards, though monitoring is not sufficiently widespread to identify them. Yet, though EPA has estimated that 15,000 lives could be saved as a result of the new standards, these have not yet been implemented. Due to the physiological effects of fine and coarse PM, BREDL recommends that EPA adopt a protocol for chemical characterization of fine particles. BREDL also recommends adopting the most protective standards, which take into account susceptible populations such as children and the elderly. Specifically, BREDL asks the CASAC to recommend a $12\mu g/m^3$ annual standard; to lower the 24-hr standard; and to set a new one-hour standard.

Dr. Anne Smith (Charles River Associates, Inc.) for the Utility Air Regulatory Group (UARG)

Dr. Smith commented on EPA's method of truncating the confidence intervals below zero, which may hide much of the probability of "no effect" (See Attachment U). A probability distribution would be a more appropriate representation of the data. She also noted that uncertainty is understated, due to failure to provide an integrated uncertainty analysis. Emphasis is instead placed on unimportant uncertainties, and the key uncertainties analysis is not statistical. An integrated uncertainty analysis was conducted using an equal-weights applied to models, and resulted in an increase in the probability of no effect – to 38%, from the 30% value computed by EPA's analysis.

Dr. Peter Valberg (Gradient Corporation) for the Engine Manufacturers Association (EMA)

Dr. Valberg commented on the recommended ambient PM ranges (see Attachment V). The quantitative analysis of major uncertainties, assumptions, and limitations in the staff paper is not adequate, and there are gaps in the logical rationale for the proposed range of the $PM_{2.5}$ annual standards. Justification for how those standards were chosen is not provided, and they do not appear to consider the results of the risk assessment. A more balanced selection of results from the scientific literature is also necessary. Questions remain on whether current models include all factors affecting mortality; on the reasons behind the heterogeneity seen over time and among different locations; on whether all fine PM constituents are equally important; and on the large disparity that exists between the proposed PM levels and toxicity no-effect levels.

Dr. Fred Lipfert

Dr. Lipfert commented that the current science presented in the staff paper is insufficient to support effective PM regulations (see Attachment W). Comparisons of the concentrations obtained from dichotomous monitors with those obtained using the FRM have revealed inconsistent measured concentrations both of PM constituents, and among different cities. In order to relate ambient concentrations to human health endpoints, more information is needed on the constituents of fine PM; without speciation data, it is possible that differences in the inclusion of some constituents may have affected the conclusions of key epidemiology studies. Effective standards cannot regulate an index (such as $PM_{2.5}$), but must regulate the individual compounds responsible for health effects.

Dr. Jon Heuss (Air Improvement Resource, Inc.) for General Motors Corporation

Dr. Heuss noted that dose plausibility, a critical issue in setting an air quality standard, has been ignored despite CASAC recommendations (see Attachment X). Large uncertainties remain in the document, particularly the fact that the existence and extent of PM association depends on model selection choices. Differences in PM toxicity can also complicate risk assessment and implementation, as the treatment of all PM as equally toxic is not appropriate. The staff paper is overly reliant on ambient epidemiology; however, issues such as publication bias, model selection, and the role of confounding factors are either ignored or down-played.

Dr. Linnea Avallone (University of Colorado) for Environmental Defense (ED)

Dr. Avallone discussed a study conducted by Environmental Defense which compared pairs of cities with identical annual mean concentration values, but different 98th percentile values (see Attachment Y). A three-year "exposure unit" (EU) value was calculated for each city. Data were presented from several city pairs showing a range of 30%-35% in differences in exposure, among cities with the same annual mean values. The majority of this difference in exposure was derived from the 2% of days with the highest concentrations, indicating that reducing the 98th percentile metric can achieve substantial benefits in decreasing exposures.

Dr. Linda Smith, California Air Resources Board (CARB)

Dr. Smith provided comments via teleconference, as well as a written statement from the CARB (see Attachment Z). While the CARB generally supports the EPA's assessment and proposed ranges for the $PM_{2.5}$ and $PM_{10-2.5}$, a wealth of studies exists that indicate health effects at the lower ends of these ranges. Adequate protection of public health therefore necessitates a standard at or near the low end of the proposed ranges. The CARB concurs also with the need for separate standards for fine and coarse PM, in light of the evidence for health effects resulting from both size fractions.

Ms. Martha Keating, Clean Air Task Force

Ms. Keating presented the recommendations of the Clean Air Task Force (Attachment AA), which supports the EPA staff's recommendation to lower the ranges for both the annual and daily $PM_{2.5}$ standards. Research published since the last NAAQS review supports this, including the NMMAPS study, American Cancer Society study, and time series studies. The Clean Air Task Force is not aware of any studies, other than those funded by industry, that justify raising the current standards. In addition, studies that have not undergone peer review ought not to be given equal consideration. The CASAC is urged to completed its review, as the EPA is under a court mandated deadline, and no scientific rationale merits further delay.

Dr. Jefferson Dickey, Greater Boston Physicians for Social Responsibility

Dr. Dickey began by commending EPA on the staff paper, adding that public health groups have compiled a set of robust data that show the association of PM with health effects. Air pollution seems to affect cardiac physiology as well as have other, disparate effects. The ranges proposed by EPA are consistent with the existing scientific evidence. Statistical approaches using dose response analysis provide appropriate scientific evidence upon which to base standards. The Agency was urged to set standards in such a way as to protect the most sensitive members of the population, including an adequate margin of safety.

Mr. Bob Yuhnke, Consultant for NRDC and Environmental Defense

Mr. Yuhnke noted the analysis presented in earlier comments by Dr. Linnea Avallone. The EPA placed primary emphasis on annual standards during it last review, with the goal of reducing total exposures based on annual means. Dr. Avallone's analysis, however, demonstrated that

different distributions of daily concentrations can result in unequal cumulative exposures over the span of a year. The CASAC and EPA were urged to consider making cumulative exposure a key element in selecting a suite of protective standards. Reanalysis was also suggested for those datasets which were truncated. In terms of the 24-hour standard, Mr. Yuhnke recommended that it be set at a concentration lower than 25 $\mu g/m^3$.

In addition, written comments were received from: the Ford Motor Company; the Appalachian Mountain Club; Ms. Sandy Adair; Dr. Suresh Moolgavkar; Mr. S. C. Peck; Dr. Paul Switzer; and the American Petroleum Institute (API). These are attached as Attachments BB through HH, respectively.

Overview Presentation on EPA's 1st Draft of the NAAQS Staff Paper for PM and Draft PM Risk Assessment

Dr. Karen Martin, 1st Draft of the NAAQS Staff Paper for PM and Draft PM RA

Dr. Martin began her presentation (see Attachment II) by reviewing the process for the review of the science included in the staff paper. CASAC review and public comments on the first draft will help inform the second draft staff paper, which will be based on the final PM criteria document. As a draft staff paper, the document does not represent Agency positions.

Dr. Martin then discussed key issues related to the PM NAAQS. In Chapter 2, key topics include the appropriateness and adequacy of the air quality information, and the presentation of this information. Chapter 3 contains characterizations of the effects associated with fine and coarse particles, as well as interpretation and presentation of the evidence for such health effects. Chapter 4 considers the overall approach, methodology, and scope for the risk assessment, and Chapter 5 the characterization of PM related welfare effects, such as visibility impairment and effects on ecosystems. Chapter 6 discusses the staff's preliminary approaches for interpreting available information for setting primary and secondary standards and developing staff recommendations on indicators, averaging times, forms, and ranges of levels for these standards.

Dr. Mary Ross, Characterization of PM Related Health Effects

Dr. Ross noted that the staff paper draws upon findings from epidemiology, toxicology, and clinical studies, and focuses on considerations relevant to the NAAQS review (see Attachment JJ). Health effects will be characterized and supporting studies presented in the document, with emphasis on research conducted in North America. For comparison purposes, figures will present results from single-pollutant models, while potential confounding issues will be discussed in the text.

Mr. Harvey Richmond, Characterization of Health Risks (Chapter 4)

Mr. Richmond reviewed background information on the current, as well as the next (2nd) draft of the risk assessment and risk assessment chapter of the staff paper, including past reviews and the goals of the risk assessment (see Attachment KK). The key assumptions, uncertainties and

limitations of the document were also listed. Characterization of health risks in the draft staff paper will begin with an explanation of the scope, methods, and selection criteria and the chapter in the staff paper includes a summary presentation of risk estimates for PM, as well as sensitivity analyses of key uncertainties and assumptions. Several key observations concerning these risk estimates were presented. EPA is also in the process of developing a probabilistic assessment approach to improve the characterization of uncertainty for health benefits, which may be useful for future NAAQS reviews.

CASAC PM Review Panel Discussion and Deliberations re: PM Staff Paper and Risk Assessment

Dr. Hopke suggested discussing the staff paper and risk assessment systematically, beginning with Chapter 3.

Chapter 3 (Characterization of PM-Related Health Effects)

Dr. Vedal commented that he would like to see a more formal approach to uncertainty in this chapter; though potential sources of uncertainty are itemized, they are not brought into the subsequent section on risk assessment. Coherence and consistency are other important topics to discuss in more detail, as is the impact of incremental increases in concentration to risk. A figure in the document (Fig. 3-12) shows a plot of the risk estimate by concentration of the confounding pollutant, yet it does not provide insight into either the presence or absence of confounding. He agreed, in response to Dr. Martin, that the figure would have more meaning in terms of effects modification, as opposed to confounding.

Dr. Miller commented on the selectivity of the studies cited from Chapter 8 of the PM CD, recommending that the evidence from all the studies be examined prior to making selections. He noted that this issue relates to Chapter 3, which contains statements of over-interpretation concerning how research supports a proposed standard. He added that the truncation of confidence limits on the graphs in the risk chapter (Chapter 4), noted earlier by some of the public commenters, represents unwarranted selection bias. He confirmed that, by selection bias, he referred to the extent to which each study was discussed – not which specific studies were chosen.

Dr. Samet recommended that the criteria used for both study selection and evidence interpretation should be stated clearly, early in the document. Explaining these criteria and the process followed would increase the transparency of the document. He also recommended clarifying the text on consistency, on pages 3-11 to 3-12.

Dr. McClellan remarked that the document could be better organized, in particular by discussing the weight of evidence as it stands today, rather than discussing research chronologically. He suggested beginning with a background section on description of risk and the nature of health effects, followed by the nature of indicators used, and how the evidence would be examined. He agreed with Dr. Samet's recommendation of stating the ground rules for study selection.

Dr. Speizer thought that the mechanisms for health effects should be better described, including the basic science and toxicology of PM, and focusing on the epidemiology data. He was also concerned that the relative lack of research and data on the effects of $PM_{10-2.5}$ was not adequately communicated.

Dr. Miller noted, and Dr. Speizer agreed, that only three out of the fourteen studies of $PM_{10-2.5}$ associations with mortality reported statistically significant results, yet the staff paper still states that the science supports development of a standard.

Dr. Lippmann replied that the staff was faced with a situation of having to make a decision, even though the existing data are not adequate. He commented that, in this case, in may not be appropriate to be bound by statistical significance.

Dr. Hopke argued that this approach would make it difficult to outline clear selection criteria for the research and data used in support of a $PM_{10-2.5}$ standard.

Mr. R. White commented that the discussion of sensitive populations should be explained to include estimates of the magnitude of these populations. On the topic of the $PM_{10-2.5}$ standard, he noted that there are more data now than during the review of the first standard. Overall, he said the quality of the staff paper was very good.

Dr. Martin asked what role precision should play in devising criteria for bringing forward the importance of study results.

Dr. Samet noted that some studies are consistent with each other, yet have wide confidence intervals. Research may need to be evaluated in terms of individual details. He added that, in general, precision would be an important criterion in selecting studies to include.

Dr. Koutrakis agreed that this chapter is well written, adding that it presents the case for a standard well. He commented that the discussion on exposure issues could be augmented to include information on confounding factors such as weather and behaviors. On the topic of toxicology, a statement is made that animal studies cannot necessarily be extrapolated to human effects; this is true, yet the majority of toxicology studies are still conducted on animal models.

Dr. Speizer and Dr. Koutrakis wanted to know if a court decision could prevent setting a PM_{10} standard, even if this was the Panel's ultimate recommendation.

Dr. Martin explained that the court had already made a judgment that having separate standards for PM_{10} and fine PM resulted in double regulation for fine particles. EPA could still propose such standards; however, it would need to provide a different explanation for why standards for both PM_{10} and $PM_{2.5}$ were appropriate. If the court were to rule in the same way, that would again result in a revoked standard. She noted that the science did seem to indicate the appropriateness of disaggregation, rather than aggregation of fine and coarse particles.

Dr. Miller commented on a statement on page 340, under the section on infant mortality. He disagreed with the assertion that data are suggestive of a causal relationship.

Dr. Hopke noted that this subject was in a section in Chapter 8 of the CD, which is still subject to revision. Thus, the outcome of the revision of the CD will presumably affect the wording here.

Dr. Vedal noted that this comment was related to the lack of clearly stated "ground rules." Unless these guidelines are described, it is difficult to define studies as providing suggestive, strong, or inadequate data.

Dr. Miller noted that, if the Bradford-Hill criteria were used on these data, they would not reveal a causal relationship.

Dr. Vedal returned to the topic of characterizing the evidence for the effects of fine versus coarse particles. The evidence for this difference in effects is based on time-series studies, but there is not a large body of toxicology data.

Dr. Lippmann noted that the evidence for effects from coarse particles is clearly less robust than for fine particles. He suggested setting a less restrictive coarse PM standard, which would still prevent worsening of local conditions and allow the creation of a data for coarse PM.

Mr. Poirot commented on the topics of consistency and coherence among selected studies. This is an important part of the logical argument presented in the staff paper, and should be more detailed and better organized. A useful component of this argument would also be to emphasize the divergent nature of particle composition.

Dr. Samet suggested a more detailed discussion of the selection of city-specific estimates, given some inherent imprecision in the estimates for specific locations. Bayesian estimates acknowledge the somewhat homogeneous nature of pollution sources across the country, and the likely similarities in physiological responses.

Dr. Hopke questioned the extent to which pollution sources are homogeneous across the country, as there are significant compositional differences among cities.

Dr. Koutrakis noted that the time series analysis shows effects for a specific change in exposure (a difference in concentration over time). However, an identical increase may have different effect at high versus low concentrations (e.g., an increase from 100 to 120, versus from 40 to 60).

Dr. Vedal noted that there has been continuous discussion on whether to regulate absolute levels, or changes in PM concentration. Based on the models, a given change in concentration will yield a given response, regardless of the concentration level.

Dr. Miller replied that this comment was related to the issue of whether a specific biological threshold exists for effects; such a threshold would be a level, not a change in concentration.

Dr. Koutrakis also commented on the link between short-term and long-term effects, which is not discussed in the staff paper.

Mr. Richmond replied that the potential overlap between the two was being considered, but added that the current data are not sufficient to fully address the topic.

Dr. Miller suggested that an appropriate statistical analysis could be used that would separate the two types of effects.

Dr. McClellan asked why the lowest and highest 5% of the monitoring data were not excluded from the risk assessment.

Dr. Samet replied that this was a technique for removing outliers from the dataset, but Dr. Hopke thought that this practice may also be removing extreme values – rather than true outliers.

Dr. McClellan noted that, at low concentrations, the concentration-response function is less accurate. He added that the top 5% of measurements should still be included.

Mr. Richmond explained that Appendix C of the draft risk assessment report lists the lowest measured levels. The lowest value used in the risk assessment was the highest of two values: background concentration, or the lowest measured concentration.

Summary, Wrap-up and Next Steps

Mr. Butterfield thanked the Panel, EPA and public commenters, and acknowledged Dr. Sverre Vedal, who would be leaving the CASAC following this meeting. Dr. James Crapo has been appointed by the Administrator as a new CASAC member.

THURSDAY, NOVEMBER 13, 2003

Reconvene Meeting, Attendance

Dr. Hopke opened the second day of the meeting, and noted that the Panel would continue its discussion on the staff paper, beginning with Chapter 4.

Continued CASAC PM Review Panel Discussion and Deliberations

Chapter 4 (Characterization of Health Risks)

Mr. R. White commented on a statement on page 431, which claims that GLM is less likely to provide the best central tendency, as opposed to GAM analysis. He noted that some researchers would disagree with this opinion.

Dr. Ross explained that GAM provides a better point estimate, while GLM was a better descriptor of the standard error.

Dr. Miller and Dr. Vedal agreed that both methods are statistically unbiased, but that it is not clear which one may be better.

Mr. R. White commented that the analysis using rollback was directed to the actual level of the proposed standard. However, many states develop air quality plans at some margin below the standard, in order to prevent exceedences.

Mr. Richmond agreed that this practice occurs, but replied that the staff did not think it appropriate to model based on how different states might implement the standards, but rather focus on the protection provided when the standards are just met for purposes of setting appropriate standards.

Dr. Miller noted a statement on page 4-35 which refers to the impact of the sensitivity analysis. The results of this analysis are not stated, however, and are difficult to find in the appendix. He also asked how the standard deviations for the IMPROVE sites were calculated.

Mr. Richmond replied that the standard deviations from all the IMPROVE sites were computed, then a standard deviation was chosen from the lower end of that range and applied to the best estimate for policy-relevant background cited in the criteria document.

Mr. Poirot noted that the analysis makes the assumption that natural influences follow the same distribution as anthropogenic influences. This does not seem to make sense, but using random association may result in cases where "natural" background exceeds anthropogenic background.

Dr. Hopke explained that policy-relevant background was defined as the sum of the contribution from all natural sources and anthropogenic sources outside of North America, which complicates this issue further.

Mr. Richmond agreed that this was a dilemma, adding that it is recognized in the document.

Public Comments

Ms. Ulla-Britt Reeves commented on the staff paper on behalf of the Clean Air and Energy advocacy group. She noted that fine PM is of particular concern in the Southeast, where air pollution remains some of the worst in the country. She recommended that EPA heed the suggestions for standards outlined in the staff paper and, at minimum, retain the current standards. The current 24-hour standard does not adequately protect public health, and it was recommended that EPA follow the lead of the state of California in setting the new standard. The Agency was also urged to set the annual standard at or below 12 $\mu g/m^3$, based on the evidence for health effects at even this low level. Ms. Reeves also agreed with the need for a separate standard for PM_{10}, although a more stringent range than the one proposed is necessary. The 98^{th} percentile standard currently allows for too many exceedence days, therefore an alternative form should be considered.

Continued CASAC PM Review Panel Discussion and Deliberations

Chapter 4, Continued Discussion

At the Panel's request, Mr. Richmond explained the truncation of the risk values below zero. This truncation was done only in the presentation of the results, because it was considered inappropriate to assume that PM has beneficial effects. There was no truncation in the calculations performed to obtain the averages.

Several Panel members stated that this should be explained more clearly in the document and that the figures should clearly present the full range of the confidence intervals.

Dr. Miller recommended dividing some of the figures in this chapter, specifically Figures 4.4 through 4.8, so that they are easier to follow. In addition, the document should state that the IMPROVE sites include areas such as national parks.

Dr. Rowe returned to the topic of the truncated figures, noting that the truncated graphs present a different message than the data. He suggested using dotted lines to represent values below zero.

Dr. Koutrakis noted that the background average point estimate on Table 4A (p. 4-26) was the same for the East and West, even though coarse PM concentrations are higher in the West. In addition, the confidence intervals are much smaller for PM_{10} than for $PM_{2.5}$, yet this is not discussed or explained in the document.

Dr. McClellan recommended including a discussion of historical changes in PM measurement techniques. This topic should be specifically addressed in Chapter 2, but its effect should be acknowledged in Chapter 4.

Dr. Vedal encouraged the incorporation of more formal probabilistic models in the future. The only uncertainty measured in the current analysis is sampling variability, which is an underestimate of the true confidence intervals.

Dr. McClellan referred to the previous day's presentation by Dr. Anne Smith, on the approaches for uncertainty analysis. He asked whether her approach could be incorporated into the staff paper's discussion of uncertainty.

Mr. Richmond replied that the staff did not feel this was appropriate at this time, as weights for each model would need to be provided. Assigning equal weight to each model is an implicit assignment, and any weight assignment should be decided by a panel of experts.

Dr. A. Smith agreed that assigning weight is a difficult process and needs to be peer-reviewed, but noted that weight has already been assigned implicitly by the choice of models included. Bias can be injected simply by which results are selected, and how frequently they are presented.

Dr. Miller agreed, noting that an attempt should be made to show the variability that could arise from such weighting.

Dr. W. White commented on the topic of background. The document concludes that different choices in estimated background could influence risk, yet that only matters if the 98th percentile daily standard is the controlling standard. For estimating background in the Eastern U.S., Dr. White suggested going back and examining the IMPROVE data and looking at how much of fine PM is non-sulfate. If one subtracts out sulfate, what remains is close to the range of background contained in the draft PM CD. Dr. Poirot agreed with this approach.

Chapter 2 (Air Quality Characterization)

Dr. Poirot noted that he had provided written editorial comments on this chapter. He also brought up a statement indicating that EPA has a policy for the exclusion of extreme natural events, and suggested explaining how such a policy would affect the percentile definitions. He added that he found the chapter to be well written overall.

Dr. Martin confirmed that EPA does have such a policy.

Dr. Zielinska agreed that the chapter provides a good summary of Chapters 2, 3 and 5 of the PM CD. She commented that the issue of background followed from the criteria document, and that the Panel had agreed previously that this is an acceptable way of dealing with background.

Dr. Hopke confirmed that, adding that the Panel had also commented that it could not come up with a better way of distinguish actual or policy-relevant background from what is actually measured in remote sites.

Dr. W. White reiterated that background could be assumed to always be lower than the ambient concentration.

Dr. Hopke replied that, though this approach could apply on an annual basis, there is still a problem with determining background on a daily basis. Some evidence exists that a large increase in concentration from one day to the next may drive health effects.

Dr. Wolff recommended that EPA consider the public comments on background provided by Drs. Hidy and Lefohn. He also noted that some of the figures, beginning with figure 2-6 and 2-7, were difficult to read.

Dr. Miller commented on the fact that the highest monitored value from a county is taken as the value for the county, a practice which would bias the risk estimate upwards.

Dr. Martin replied that this was not done for the risk assessment. Mr. Richmond added that, in this chapter, this practice was used to determine the amount of rollback because most areas plan to use the highest monitored value — rather than a composite average in determining attainment. The information on an alternative approach to rollback was presented to show the difference that could result from using one approach over the other, but it was not factored into the risk results. Mr. Richmond explained that while the amount of rollback was determined based on the highest monitor in a study area, all of the available monitoring data, not just the highest monitor in a

county, were used to calculate a composite daily value that was then rolled back in the risk assessment calculation.

Dr. Hopke recommended that this explanation be made clearer in the document.

Mr. Poirot suggested adding that the figures in Chapter 2 are reflective of attainment values, given than most areas have chosen not to use spatial averaging. He commented that having that option, however, results in different metrics used to apply to the same standard.

Dr. Miller agreed, saying that it was unacceptable not to use all the available data.

Dr. Koutrakis noted that, in comparing fine and coarse PM, it is important to remember that coarse particles are much less likely to reach the lungs than fine particles. The discussion of exposure should include issues such as the difference between acute and chronic exposures and time resolution. It should also acknowledge the fact that exposure may be very different than measured ambient concentrations. Finally, the discussion of visibility is of academic importance, yet little information on effects is known so it cannot be used for regulation.

Dr. Hopke explained that this section (Section 2.9) is intended to lay the base for a later discussion on welfare and ecosystem effects evaluation (Chapter 5). He agreed with Dr. Koutrakis' comment that it may need additional information in order to do so successfully.

Dr. W. White suggested including two different sections, and making a clear distinction between radiation and visibility. Dr. Martin agreed that such a distinction would be appropriate.

Dr. Koutrakis then pointed out a discrepancy in the terminology used, specifically use of the term "10 minus 2.5", versus the phrase "particles between 2.5 and 10 microns", which is more commonly encountered in the literature.

Dr. Hopke and other Panel members agreed that it was more important to use one of the two terms consistently throughout the document.

Dr. McClellan reiterated a point made earlier, stating that a discussion on the historical changes in PM monitoring techniques would be helpful for later sections of the document. He also cautioned the staff to be cautious in its use of language throughout the staff paper. On the topic of nomenclature, he noted that some differences arise from whether the term refers to particle size, or to how the particles behave.

Dr. Hopke agreed terminology should be clear between particle size modes and particle measurement size classes.

Chapter 5 (Characterization of PM-Related Welfare Effects)

The Panel then moved to a discussion of Chapter 5, whose topic is welfare and ecological effects.

Dr. Legge commented that the section on ecological effects was well put together overall. However, there is a major problem with relating these effects to PM, as neither a 24-hour nor an annual standard reflects the way in which ecosystems respond. Unlike human health, there is no debate on whether PM is having an effect on ecosystems. Effects on ecosystems are reflected in nitrate leaching, for example, but they are a result of very long term nitrogen saturation. PM is not an appropriate measure for protection of forest ecosystems that have nitrogen loading problems, as ecosystems respond to many stressors, rather than just particulate matter. From a legislative perspective, looking at air pollutants in isolation is not a viable way of protecting ecosystems.

Dr. Martin replied that, for the purpose of the staff paper, this discussion is intended to outline the relevant science. Another purpose of including it is to make the case that there is not sufficient science to derive a regulatory tool, therefore other policy tools should be developed.

Dr. Speizer noted that the document could suggest PM as a surrogate for anthropomorphic-related combustion. Reducing the surrogate could have an effect on improving ecosystem health.

Dr. Legge responded that the latter statement could not be supported by the existing science.

Dr. Lippmann asked whether the impact of PM reductions on nitrogen loading could be estimated. If so, this could indirectly provide a measure of ecosystem effects.

Mr. Poirot noted that the staff paper may be limited to effects of PM deposited to ecosystems in particle form – rather than those that are then removed by wet processes. Also, it is unclear whether the document is restricted to PM, or whether their gaseous precursors can also be taken into account. If a secondary standard is being considered, overall deposition could be used as an appropriate integrator. He suggested that the discussion in the staff paper be inclusive of particles, regardless of the manner in which they are deposited, as well as of their precursors.

Dr. Zielinska remarked that, in the case of nitrogen loading, secondary products may be more important in impacting ecosystems than PM.

Dr. Miller asked whether portions of the ecosystem load could be quantified, so that the problem can be dissected into components that can be reduced, and the proportion of the impact they represent.

Dr. Legge replied that nitrogen coming into the system can be measured. If the critical load can also be estimated, then an estimate of how much emissions should be reduced is possible. In many systems, however, nitrate leaching is already occurring.

Dr. Hopke added that the national scale of the standard could also present a problem with setting the level of protection – i.e., whether it should be set for the most sensitive ecosystems.

Dr. Legge stated that the European approach is to use a "target load." This is a load that is politically and economically acceptable, yet it may be different than the critical load, below which there are no adverse effects on a system.

Dr. W. White remarked that a secondary standard can be set closer to where it should be, given that states do not have to comply. A strict secondary standard could therefore be set, along with an acknowledgement of the economic impact it may have on states.

Dr. Martin explained that states are required to meet the secondary standards, though not within the same time frame as primary standards. She added that cost is precluded from consideration in setting even the secondary standards.

Dr. Rowe commented that economic valuation studies would be useful in this chapter, particularly in justifying the need for a secondary standard for welfare/ecological effects.

Mr. Poirot commented on visibility, saying that he understood the logic of not considering a secondary standard for visibility: only limited information is currently available, but the potential to use these data to quantify relationships will be remarkable in the near future. On the other hand, numerous states already have visibility standards. These tend to converge around the value of 50km, which is estimated to be equivalent to a fine PM level of 15$\mu g/m^3$. This could be referred to in the next section of the document as an additional benefit of setting this standard toward the low end of the proposed range.

Dr. W. White noted that the discussion of visibility is separate from that on health effects; however, fine particles are what visibility represents ("what you see is what you breathe"). He suggested illustrating this point by matching different levels of fine PM with an image depicting visibility at that level. This connection should be more clearly explained.

Dr. Rowe countered that visibility is more an issue of public perception, whereas the information on health effects is derived from epidemiology studies.

Dr. W. White thought that the two chapters should at minimum cross-reference. A case can also be made for fine particle haze being the end result of anything emitted into the atmosphere.

Dr. Martin cautioned that no implication can be made that visibility improvements would translate to a reduction in health effects.

Mr. Poirot noted that the staff paper presents regional haze regulations somewhat optimistically, as these are frequently voluntary regulations based on good will – there is no guarantee they will lead to improvements in visibility.

Dr. Speizer questioned the lack of economic valuation studies, and gave the effects of soiling as an example of the type of information that could augment the economic analysis.

Dr. Martin replied that such studies would be considered in the regulatory impact analysis. For the staff paper, however, they may be inappropriate: a study on the economic costs of cleaning

monuments, for example, provides no information on which PM concentrations could result in more or less cleaning.

Chapter 6 (Staff Conclusions and Recommendations on PM NAAQS)

Dr. Hopke asked the Panel to begin the discussion of Chapter 6, but cautioned that some aspects of it may change upon completion of the criteria document and risk assessment.

Dr. Vedal discussed the selection of the controlling standard, versus the supplemental standard, and agreed with using the annual average as the controlling standard. However, he could not see a logical link between mean annual concentrations in the time-series studies, and the annual standard, given that it is difficult in these studies to know the concentration at which the effect is seen. An alternative approach is to focus on the cohort studies; in the document, however, these are brought in only as supplemental support for the range of choices made based on the time series studies.

Dr. Martin replied that using the time-series studies as a basis to set a long term standard is appropriate because most of the risk is derived from the central part of the concentration distribution. A reasonable approach to reduce risk would be to attempt to shift the entire distribution curve; this can be better accomplished through an annual standard.

Dr. Vedal said that he accepted this as a practical solution, but added that a mean can signify different things depending on the time distribution of concentrations within a city.

Dr. Miller asked what the accepted standard deviation was for the Federal Reference Method for $PM_{2.5}$. Several Panel members confirmed it was better than 10%. Dr. Miller and Dr. Hopke agreed these numbers would be helpful to include in the next draft.

Dr. Vedal then commented on the meager amount of information available on the health effects of coarse PM. Whether a standard can be set depends on the confidence the Agency has on this database.

Dr. Martin replied that it may well be appropriate to set a standard based on existing information, although limited, recognizing that the standard can be revised in subsequent reviews as additional data become available.

Dr. McClellan suggested adding some alternative approaches to setting standards. The approach used is clearly described, but it is not directly health-based. On the topic of $PM_{10-2.5}$, he noted that the limited data available do not clearly drive the preliminary staff recommendations of ranges for a standard. The relative strengths of the databases used for PM_{10}, $PM_{10-2.5}$, and $PM_{2.5}$ should be discussed in this section.

Dr. Lippman replied that the Agency may not want to relax its ability to control coarse particles. The database for PM_{10} can be corrected for $PM_{2.5}$ to provide a reasonable amount of information, as well as to rationalize the same degree of protection.

Dr. Vedal agreed with not relaxing coarse standards, but noted that much of the current information is driven by fine PM, and does not provide much insight into the coarse fraction effects.

Dr. Lippman agreed that data point to $PM_{2.5}$ as the most important part of exposure in terms of mortality. Coarse particles do affect certain other health endpoints, however. As these are more acute, irritation-based responses, they could provide some rationale for a 24-hour coarse standard.

Dr. Miller agreed, and commented that no monitoring sampler can mimic the collection of particulate matter in the respiratory tract.

Mr. R. White expressed concern about the potential for repeated acute disease to drive disease progression, particularly in susceptible populations. If this is the case, then it provides a rationale for setting a long-term standard. He stated that it was the combination between the level and the form of the standard that would ultimately provide protection. Finally, he encouraged the Agency to consider Dr. Avallone's presentation of the previous day and examine the possible implications of differences in exposure among cities with identical annual averages.

Dr. W. White replied that the exposure units presented by Dr. Avallone were derived by disregarding concentrations below 10 $\mu g/m^3$. He then commented on the issue of background as it relates to the coarse PM 24-hour standard. The current method for monitoring coarse PM is particularly "noisy." A newly-developed continuous monitor for coarse PM may provide a more solid basis for enforcing the standard.

Mr. Poirot commented that the nature of some distributions may warrant a 24-hour standard – such as for sites with large day-to-day changes in the concentration. A 24-hour standard could be set in addition to the annual average.

Dr. Miller brought up the difference between a functional threshold versus a biological threshold; log-linear models cannot demonstrate the existence of an effective biological threshold. Epidemiology studies should take into account alternative models, rather than enforcing an aspect of Haber's law which does not hold true for some biological events.

Dr. Lippmann said he understood Dr. Miller's comment, but added that the discussion must make clear these responses are seen in a small percentage of the population. The concept of threshold for population-based responses is different from the concept as it is used in standard toxicology. He suggested that the staff paper address this distinction in more detail.

Dr. Wolff stated that he was not convinced by the arguments presented thus far for deriving the range for both standards. He recommended that the Panel not limit its consideration to the range proposed by EPA, but also include the ranges of the existing standards.

Dr. McClellan commented that the staff paper should improve its exposition of baseline health statistics.

Dr. Hopke asked Dr. Martin if she had any final questions for the Panel. She did not, but stated that the discussion has been helpful and has expanded the range of topics that staff will examine in the next draft staff paper.

Summary, Wrap-up, Next Steps and Closing Remarks

Dr. Hopke asked the Panel members to submit any final comments by Tuesday, November 17 [moved back from the date suggested the previous day, Sunday 11/16), adding that he would try to incorporate these comments and send a revised version of the Panel report by the following Friday (November 21).

A conference call is planned for mid-January 2004 to discuss Chapters 7 and 8, as well as a meeting around the beginning of March 2004 to review Chapter 9. Additional review of Chapter 9, if appropriate, could take place in a teleconference in late March or early April 2004.

Once the criteria document review is final, the Panel will move on to the second draft of the staff paper, which is expected to available about two months following the completion of the CD. The Panel meeting on the second draft staff paper would likely occur around the end of August 2004.

Action Items:

- Dr. Hopke will send the final version of the Panel's report from the August 2003 meeting to all Panel members on Friday, November 14.
- Comments from Panel members on the final August 2003 meeting report are due to the Chair by Tuesday, November 18, 2003.
- Dr. Hopke will incorporate the comments and send a revised report by Friday, November 21, 2003.
- The official August 2003 meeting Panel report will be submitted to the Agency the week of November 24, 2003.
- Dr. Miller will send the dates of the Society of Toxicology 2004 meeting to the DFO.
- A teleconference to discuss Chapters 7& 8 is planned for mid-January 2004.
- A meeting to discuss Chapter 9 is planned for around the beginning of March 2004.
- A teleconference to further discuss Chapter 9 may take place in March or April 2004.
- A meeting to review the 2nd draft staff paper may be planned for August 2004.

Respectfully Submitted:

[Fred A. Butterfield, III]

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Fred A. Butterfield, III
CASAC Designated Federal Officer

Certified as True:

[Philip Hopke, Ph.D.]

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Philip Hopke, Ph.D.
CASAC Chair

ATTACHMENTS

Attachment A:	Roster of the CASAC Particulate Matter Review Panel
Attachment B:	Teleconference Agenda
Attachment C:	Federal Register Notice
Attachment D:	Participant Sign-In Sheet
Attachment E:	Update on PM NAAQS Review Schedule as of 11/12/2003
Attachment F:	PowerPoint Slides, Les Grant: Revisions to 4th draft AQCD
Attachment G:	PowerPoint Slides, William Wilson: Model Comparisons
Attachment H:	PowerPoint Slides, Dan Costa: Inhalation/Instillation Studies
Attachment I:	List of Public Speakers
Attachment J:	Public Comments: Dr. Jay Turim
Attachment K:	Public Comments: Dr. John Richards
Attachment L:	Public Comments: Mr. Greg Shaefer
Attachment M	Public Comments: Mr. Robert Connery
Attachment N:	Public Comments: Dr. Allen Lefohn
Attachment O:	Public Comments: Mr. Stanley R. Hayes
Attachment P:	Public Comments: Dr. Ron Wyzga
Attachment Q:	Public Comments: Dr. Rebecca Klemm
Attachment R:	Public Comments: Dr. Laura Green
Attachment S:	Public Comments: Mr. Phillip Johnson
Attachment T:	Public Comments: Mr. Louis Zeller
Attachment U:	Public Comments: Dr. Anne Smith
Attachment V:	Public Comments: Engine Manufacturers Association (includes cover letter, and comments by Drs. George Hidy, Bruce Allen & Kenny Crump, and Peter Valberg).
Attachment W:	Public Comments: Dr. Fred Lipfert
Attachment X:	Public Comments: Mr. Jon Heuss (PowerPoint Slides and report)
Attachment Y:	Public Comments: Dr. Linnea A. Avallone
Attachment Z:	Public Comments: California Air Resources Board (CARB)
Attachment AA:	Public Comments: Ms. Martha Keating
Attachment BB:	Written Comments: Ford Motor Company
Attachment CC:	Written Comments: Appalachian Mountain Club
Attachment DD:	Written Comments: Ms. Sandy Adair
Attachment EE:	Written Comments: Dr. Suresh Moolgavkar
Attachment FF:	Written Comments: Mr. S. C. Peck
Attachment GG:	Written Comments: Dr. Paul Switzer
Attachment HH:	Written Comments: American Petroleum Institute (API)
Attachment II:	PowerPoint Slides, Karen Martin: 1st Draft of NAAQS Staff Paper
Attachment JJ:	PowerPoint Slides, Mary Ross: Characterization of PM Health Effects
Attachment KK:	PowerPoint Slides, Harvey Richmond: Characterization of Health Risks